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09/898,165	07/02/2001	Daniel H. Cohn	18810-81552	7056

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/398165

Applicant(s)

Cohn et al.

Examiner

T. Sridha

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/27/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 109-111 and 114-115 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 109-111 and 114-115 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. ***Election***

Applicant's election *without traverse* of Group I (claims 109-111 & 114-115, drawn to human PAPS synthetase of SEQ ID NO : 7 (encoded by SEQ ID NO : 9) and cancellation of non-elected claims in Paper No. 14 is acknowledged.

2. The Preliminary Amendment (Paper No. 14) filed 5.27.03 has also been entered.

3. Claims 109-111 & 114-115 are pending and under consideration in this examination.

4. ***Drawings***

The Draftsman's objection(s) to the drawings is enclosed here in the notice on form PTO-948. Correction is required.

5. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. ***Claim Objections***

Claims 109-111 are objected to because of the following informalities: The claims recite SEQ ID NO : with dashes and dots.

The correct recitation will be, for example, SEQ ID NO : 7.

Appropriate correction is required.

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7. ***Claim Rejections - 35 U.S.C. § 112*** (first paragraph)

Claims 110-111 & 114-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 110-111 & 114-115 are directed to an isolated PAPSS2 fusion protein (or PAPS synthetase which is known to have bi-functional ATP-sulfurylase and APS-kinase activities; or the sulfate activating enzymes) comprising a polypeptide having an amino acid sequence of SEQ ID NO : 7, or 'gene-specific antibody binding fragment thereof at least 6 amino acids long'. The specification discloses that SEQ ID NO : 7, however, there is no description of what a 'gene-specific antibody binding fragment thereof at least 6 amino acids long' is meant to be. While antibodies are made against a protein, no binding fragment of the antibody against the gene or DNA or SEQ ID NO : 9 is described. No specific examples are presented to describe such a construct. The prior art is silent about such or similar constructs that a skilled artisan could use in order to practice such an invention. The specification does not describe in clear terms even a single or representative number of species to the genus of fusion proteins using 6 amino acid fragments of SEQ ID NO : 7. A 'representative number of species' requires that the species which are expressly described be representative of the entire genus. Therefore, without a clear description of even a single functional fusion peptide construct having the ATP-sulfurylase and APS kinase activities or

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that encoded by the nucleic acid of SEQ ID NO : 9, adequate written description of the genus is not achieved by disclosing a vague genus. Therefore, the written description requirement is not satisfied.

8. ***Claim Rejections - 35 U.S.C. § 112 (second paragraph)***

Claims 110-111 & 114-115 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 110 recites 'gene-specific antibody binding fragment thereof at least 6 amino acids long'. The claim is indefinite for it is not clear what is meant by the expression 'gene-specific antibody binding fragment'. While antibodies are generated against a protein, its specificity to a gene is unclear.

Claims 111 & 114-115 are included in the rejection for failing to correct the defect present in the base claim(s).

9. Claims 109-111 & 114-115 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 109-110 recite uncommon abbreviations 'PAPS' and 'PAPSS2', the first use of which be written in full, and which may be subsequently abbreviated.

Claim 111, line 3, recite 'gene specific fragment thereof'. Preceding this phrase is the reference to a 'nucleotide sequence'. The claim is confusing as the recitation '... thereof' is

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inappropriate. Changing the expression 'gene specific fragment thereof' to 'a fragment thereof' will overcome this rejection

Claims 114-115 are included in the rejection for failing to correct the defect present in the base claim(s).

10. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 109 is rejected under 35 U.S.C. 102(a) as being anticipated by Fatyaz ul Haque et al. [Nat. Genet. 20(2), 157-162 (1998, October), IDS]. Fatyaz ul Haque et al. teach cloning and isolation of DNA encoding human ATP-sulfurylase/APS kinase (PAPSS2) or PAPS synthetase. Applicants' nucleic acid sequence of SEQ ID NO : 9 is identical to accession number AF091242 disclosed in the reference. Applicants' SEQ ID NO : 7 is encoded by SEQ ID NO : 9 and the translated sequence is taught by the cited reference. See the enclosed sequence search alignments

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between SEQ ID NO : 9 and (Accession No. AF091242). Being identical therefore, the translated protein sequence will read upon any fragment at least 6 amino acid long or the entire length of SEQ ID NO : 7 to which an antibody can bind. The reference teaching all the claim limitations anticipates the claims. The reference has been applied in this rejection because the inventive entity of the instant application is different from that of the reference.

11. Claim 109 is rejected under 35 U.S.C. 102(a) as being by anticipated by Franzon et al. [International journal of biochemistry & Cell Biol. 31 (May 1999) 613-626]. Franzon et al. teach isolation and characterization of nucleotide and the predicted amino acid sequence from human **PAPSS2** cDNA [See page 619, Figure 2 and the abstract and the enclosed sequence alignment between Applicants' SEQ ID NO : 9 and Accession No. AF074331 of Franzon et al.].

12. Claim 109 is rejected under 35 U.S.C. 102(b) as being by anticipated by Rosenthal et al. [Gene 165 : 243-248 (1995)]. Rosenthal et al. teach a PAPS synthetase sequence which is 72.4% similar to Applicants SEQ ID NO : 7 and contains several more than 6 contiguous amino acid fragments (even though the claim does not specify the 6 amino acid fragments to be contiguous) and therefore reads upon the limitations of claim. The cited reference anticipates because it teaches the fragment limitations of the claim.

13. Claim 109 is rejected under 35 U.S.C. 102(e) as being by anticipated by Falco et al. [U.S.P. 6,338,966]. Falco et al. teach a amino acid sequence which is similar to Applicants SEQ ID NO : 7 and contains several more than 6 contiguous amino acid fragments (even though the claim does not

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specify) and therefore reads on the fragment limitation of claim. The cited reference anticipates the claim.

14. ***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 110-111 & 114-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fatyaz ul Haque et al. [Nat. Genet. 20(2), 157-162 (1998, October), **IDS**] or Franzon et al. [International journal of biochemistry & Cell Biol. 31 (May 1999) 613-626, **IDS**] and Fawell et al. [PNAS USA, 91 : 664-668 (1994)].

Claims 110-111 & 114-115 are rejected under 35 U.S.C. 102(e) as being anticipated by Fatyaz ul Haque et al. [Nat. Genet. 20(2), 157-162 (1998, October)] or Franzon et al. [International journal of biochemistry & Cell Biol. 31 (May 1999) 613-626] and Fawell et al. [PNAS USA, 91 : 664-668 (1994)]. The teachings of Fatyaz ul Haque et al. or Franzon et al. Are described above in item 10 or 11. Fatyaz ul Haque et al. or Franzon et al. Do not teach making a fusion protein.

Addition or linking of a heterologous polypeptide to make a fusion protein (by forming a hybrid gene) is well know in the art, such as adding a histidine tag, or Tat-mediated delivery of

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heterologous proteins into cells using TAT protein of human immunodeficiency virus by chemically cross-linking (Fawell et al. See abstract) or by gene fusion (Fawell et al., page 668, column 1, last paragraph) and a skilled artisan would have been motivated to do so in order to achieve a faster and easier method for protein purification (by histidine tag) or by a fusion construct using TAT protein for easier, targeted and efficient delivery of proteins into cells, and therefore an obvious modification. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, *prima facie* obvious.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Tekchand Saidha

Primary Examiner, Art Unit 1652

July 16, 2003